



News Release

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Commissioner

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Department of Health and Senior Services Proposes to Readopt N.J.A.C. 8:44 Governing Clinical Laboratories and Reproposes to Readopt N.J.A.C. 8:45, Governing Clinical Laboratory Improvement Services

The Clinical Laboratory Improvement Services of the Division of Public Health and Environmental Laboratories of the Public Health Services Branch of the Department of Health and Senior Services (Department) is proposing the readoption of N.J.A.C. 8:44, Clinical Laboratory Improvement Services and is reproposing the readoption of N.J.A.C. 8:45, Clinical Laboratories. The two companion notices of proposal appear in the June 19, 2006 issue of the New Jersey Register.

N.J.A.C. 8:45, Clinical Laboratory Services, establishes licensure requirements and fee schedules applicable to clinical laboratories. In April 2005, the Department of Health and Senior Services (Department) proposed to readopt N.J.A.C. 8:45. That proposal lapsed; therefore, the Department is reproposing to readopt that chapter without amendment. N.J.A.C. 8:44, also known as Chapter IV of the State Sanitary Code, establishes requirements for the operation of clinical laboratories. The Department is proposing to readopt that chapter without amendment.

The Department is preparing a notice of proposal to repeal N.J.A.C. 8:44 and 8:45 and to propose new rules combining the two chapters into one chapter, with appropriate revisions to update the existing requirements to bring the Department's clinical laboratory standards into compliance with recent amendments to Federal standards governing clinical laboratories. The proposed readoption without change of the existing rules at N.J.A.C. 8:44 and 45 would maintain their effectiveness and the public health protections they provide, pending the conclusion of the anticipated rulemaking to merge the two chapters.

The Department will convene a public hearing limited to the topic of the proposed readoption of N.J.A.C. 8:44 at 11:00 a.m. on Monday, July 10, 2006 at the New Jersey Department of Health and Senior Services, First Floor Auditorium, Health and Agriculture Building, 369 South Warren Street (at Market Street), Trenton, NJ 08608. Persons wishing to testify at the public hearing who wish to be placed on the list of speakers are requested to telephone Ms Davis at (609) 292-9382 by Wednesday, July 5, 2006, and to bring an extra written copy of their remarks for submission to the public record.

The public has until August 18, 2006 to comment on the proposals. Persons wishing to comment on either the proposal or the reproposal must submit their comments in writing to Dennis P. McDonough, M.P.H., Director, Clinical Laboratory Improvement Services, Division of Public Health and Environmental Laboratories, Public Health Protection and Emergency Preparedness Branch, Department of Health and Senior Services, P O Box 361, Trenton, NJ 08625-0361. Written comments must be postmarked on or before August 18, 2006, which is the close of the 60-day public comment period.

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